INFANT NUTRITION COUNCIL
AUSTRALIA & NEW ZEALAND

2 September 2021

INC SUBMISSION ON PROPOSAL P1028 REVIEW OF INFANT FORMULA: Consultation Paper No.2/2021

This submission has been prepared by the Infant Nutrition Council (INC). The INC represents the majority of companies marketing and/or manufacturing infant formula products and toddler milk drinks (formulated supplementary foods for young children) in Australia and New Zealand. INC aims to:

1. Improve infant nutrition by supporting the public health goals for the protection and promotion of breastfeeding and, when needed, infant formula as the only suitable alternative; and
2. Represent the infant formula product and toddler milk drink industry in Australia and New Zealand.

INC is a responsible group that voluntarily restricts its marketing practices for infant formula products to support government policies for the protection and promotion of breastfeeding.

INC believes that breastfeeding is the normal way to feed infants as it has numerous benefits for both mothers and babies. When an infant is not given breast milk the only suitable and safe alternative is a scientifically developed infant formula product. For these infants, infant formula is the sole source of nutrition for around the first 6 months. It is important that scientific advances in infant nutrition are captured and incorporated into these products to ensure the best possible outcome for infants who do not receive breast milk.

We welcome the opportunity to provide written comment to Food Standards Australia New Zealand (FSANZ) in response to the *Proposal P1028 Review of Infant Formula: Consultation Paper No.2/2021.*

Yours sincerely

Jan Carey
Chief Executive Officer

PROPOSAL P1028 REVIEW OF INFANT FORMULA Consultation Paper No.2/2021

Submission from the Australia New Zealand Infant Nutrition Council

2 September 2021

Executive Summary

1. INC welcomes the opportunity to consider the issues and preliminary views proposed in this Second Consultation Paper in 2021 for Proposal P1028, and to provide comment and information to Food Standards Australia New Zealand (**FSANZ**) relating to the Consultation Paper (**CP2**) on the Regulation of Infant Formula.

2. INC believes that breast feeding is the normal way to feed infants as it has numerous benefits for both mothers and babies. When an infant is not given breastmilk the only suitable and safe alternative is a scientifically developed infant formula.

3. To ensure the best possible nutrition for non-breastfed infants, policy and regulatory instruments must ensure a balance between restrictions on use and formulation in order to protect public health, and provide flexibility and incentive for innovation for continuous improvement of infant formulas.

4. Our key concerns relate to protein, certain fats and micronutrients although we raise others not covered in CP2 at the outset and conclusion.

5. In relation to protein, INC agrees with the FSANZ proposal for a protein range of 0.43 – 0.72 g/100kJ for infant formula (based on the equivalence factor of 1 kcal = 4.18 kJ) However, INC opposes this range being applied only to cows' milk-based formulas. INC recommends that this range is applied to all milk-based infant formula. The technical correction of the FSANZ minimum allows harmonisation with Codex and EU recipes, particularly for low protein products. INC has expanded the maximum from 0.7 to 0.72g/100kJ to reflect its preference for the use of at least 2 significant figures.

6. INC suggests that consideration be given to the potential for use of plant proteins other than soy for the future. For this, FSANZ may wish to consider adding a footnote similar to footnote 5 in Codex STAN 72-1981 which highlights that other minimum values may need to apply for formulas based on other non-milk proteins. Such a footnote signals that the appropriate protein minimum needs consideration for plant proteins other than soy.

7. INC does not support FSANZ's proposed approach to prescribe permitted protein sources. FSANZ's stated goal is to align with Codex to the greatest extent possible, yet this approach to prescription is not aligned with the Codex approach. INC would support therefore aligning with the Codex STAN 72-1981 definition of infant formula as a product based on:

   'milk of cows or other animals or mixture thereof and other ingredients proven to be suitable for infant feeding'.

8. New sources of protein are already required to be approved through the pre-market assessment process and therefore have the opportunity to be risk assessed prior to use. There is no additional benefit from prescribing sources other than to delay use and make work for both Government and industry in relation to maintenance.

9. INC notes that there are infant formula products in the market using protein sources which are not included in the sample of a prescribed list of permitted proteins proposed by FSANZ for example other animal milk such as sheep milk and other plant-based protein such as rice. It is also currently unclear how the prescribed protein source list would relate to Infant Formula Products for Special Dietary Use (**IFPSDU**).

10. Turning to nitrogen conversion factors (**NCF**), the amount of protein source needed to achieve the prescribed protein minimum depends on the NCF that is used. Australian and New Zealand infant formula manufacturers have been managing the use of the two alternative NCF of 6.38 and 6.25 for milk-based formulas, since the 2007 revision of the Codex STAN 72-1981 which adopted the use of the factor 6.25 for infant formula products.

11. Adopting the Codex factor is proposed as one option by FSANZ with a second option comprising all three NCF (5.71, 6.25, 6.38). At this stage, INC favours adoption of 6.25 and alignment with the Codex STAN 72-1981 NCF footnote for all infant formula products. This will achieve harmonisation with international standards and have fewer issues to work through for implementation than Option 2 as currently outlined. We note Option 2 also has the potential to achieve harmonisation, however INC does not support prescribing different NCF for whey-based vs other dairy formula.

12. Maintaining the current linoleic acid (**LA**) levels at 90 mg/100kJ is supported by INC which allows for the lower end of the LA:α linolenic acid (**ALA**) ratio of 5:1 to be achieved.

13. INC supports docosahexaenoic acid (**DHA**) remaining optional together with the requirement of DHA being no higher than arachidonic acid (**AA**) when added. However, the guidance upper limit (**GUL**) should be increased from 0.5 to 1.0% of fat equivalent to 14 mg/100kJ.

14. In relation to total phospholipids, we can support Option 1 (restrict the phospholipids content to 2 g/L) to align with Codex with modification to reflect this as a GUL. We similarly prefer alignment with Codex units which expresses total phospholipids on a mg/100kcal basis.

15. Lecithin is a food additive but was not discussed in the first Consultation Paper issued by FSANZ in 2021. INC has strong reservations about lowering the maximum permitted level in infant formula from 5 g/L to 1 g/L in the absence of a FSANZ food additive assessment, especially given that this would not be aligned with Codex.

16. The maintenance of the current restriction on medium chain triglycerides (**MCT**) is not supported by INC and is not aligned to Codex or EU. If this is to remain, it should be clarified as relating only to refined MCT oil.

17. On micronutrients, our main concerns are around the following:

    - *Iron* – INC requests that FSANZ widen the range for infant formula to include the Codex minimum (0.11 mg/100kJ) to give flexibility for recipe harmonisation. There is a lack of international alignment with the proposed minimum which creates a barrier to trade.

    - *Iodine* – INC strongly supports aligning the iodine minimum and upper level to the Codex STAN 72-1981 minimum of 2.5 µg/100kJ and GUL of 14 µg/100kJ. Manufacturers will otherwise have difficulty meeting the proposed tighter range.

    - *Selenium* – INC supports increasing the selenium minimum to 0.48 µg/100kJ which aligns with the revised Codex Follow-up Formula (FuF) for Older Infants provision. However, aligning with the EU maximum of 2.0 µg/100kJ is problematic when the maximum in Codex STAN 72-1981 and the new Codex Follow-up Formula for Older Infants provides a GUL of 2.2 µg/100kJ.

- *Fluoride* – INC supports aligning with the Codex maximum of 24 µg/100kJ but removing the phrase "when reconstituted and prepared ready for consumption", as manufacturers have no control over water and this is ambiguous to interpret and enforce.

- *L-carnitine* – INC is concerned about the inclusion of a GUL for L-carnitine and supports this being removed to align with Codex and the EU.

18. In areas not canvassed by CP2:

    - INC recommends the removal of the current limit on potential renal solute load for follow-on formulas at the same time as changes are introduced in relation to infant formula implementing the outcomes of P1028.

    - INC continues to identify the significant inconsistency in conversion factors. Inconsistent conversion factors may introduce international trade barriers, which are of concern to the INC. This review provides the opportunity to correct and clarify the Australia New Zealand position on conversion factors.

    - INC is generally opposed to positive lists on the basis that they inhibit innovation (they are rarely current) and they are a 'make work' proposition for both Government and industry.

    - INC recommends that the term 'GUL' is used and defined (as described in CP2) within the Australia New Zealand Food Standards Code (the **Food Standards Code**) for the guideline maximum amounts included.

19. INC continues to find the approach taken for nutrients permitted for voluntary addition frustrating. Use of the term 'optional ingredients', as used in Codex, is much preferred to 'may be used as a nutritive substance'. It is recommended that this is reconsidered as part of this review.

20. INC also highlights that anomalies have developed within the Food Standards Code as requirements have developed for different forms of unavailable carbohydrates. Some oligosaccharides are classified as nutritive substances and others are not. Similarly, some are considered to be dietary fibre and others not. It is recommended that these be addressed as part of this Review.

21. We draw attention to the extent of change proposed by the Review – noting there is more to come – which will result in reformulation of almost all infant formula products in the market. This will take significant time and resources for all companies that sell and manufacture infant formula in Australia and New Zealand. There are a large number of proposed changes and every infant formula product will need to be fully assessed once the revised Standard is finalised to determine the extent of reformulation required.

22. INC notes that FSANZ has conducted a label review against nutrient levels, however this is not reflective of the manufacturing levels, as the target and range must consider variance from operations, testing, raw ingredients and degradation across shelf life. Therefore, any change, no matter how small, that increases the minimum or decreases the maximum or GUL may require some change in the formulation and manufacturing specification.

23. We have enclosed with this submission, a table that sets out, for each nutrient, the levels in the relevant Codex Standard, the EU Regulations, the Australia New Zealand Food Standards Code, FSANZ proposals in CP2 and INC proposals.

24. By way of example some of the changes just to composition are:

- mandatory requirements introduced for choline, inositol and L-carnitine
- reduced energy maximum and total fat maximum
- increased minimum for pantothenic acid, folic acid, selenium, iodine and L-carnitine
- reduced maximum for sodium and potassium and
- the GULs reducing for magnesium, copper, zinc, biotin and niacin.

25. Also, there are the changes to amino acids and, as mentioned, these could impact fortification of methionine.

26. In addition to the massive task of reformulating nutrient composition, there are also proposed changes in the first 2021 Consultation Paper for additives, contaminants and labelling.

27. INC proposes a minimum transition period of 5 years followed by a stock-in-trade period. INC considers this would be appropriate given the significant number of changes proposed and the cost it will take companies to implement. This transition and stock-in-trade period will help ensure companies are able to plan to try and avoid unnecessary additional costs from labels and other food-related wastage (e.g. ingredients with change of formulation, non-compliant product). It will be important for the proposed amendments and the current arrangements to operate in parallel, for the transition period.

Introduction

1. INC welcomes the opportunity to consider the issues and preliminary views proposed in this second 2021 consultation paper for Proposal P1028, and to provide comment and information to FSANZ relating to CP2 on the Regulation of Infant Formula.

2. INC believes that breast feeding is the normal way to feed infants as it has numerous benefits for both mothers and babies. When an infant is not given breastmilk the only suitable and safe alternative is a scientifically developed infant formula.

3. To ensure the best possible nutrition for non-breastfed infants, policy and regulatory instruments must ensure a balance between restrictions on use and formulation in order to protect public health and provide flexibility and incentive for innovation for continuous improvement of infant formulas.

4. INC considers that the key elements in policies and regulations governing infant formula must allow for:
   - consistency with the policy objectives outlined in other food-related policy decisions
   - the provision of a safe and nutritious food
   - a scientific, evidence-based approach which does not unnecessarily restrict the use of ingredients considered to be safe for use in general foods in infant formula
   - flexible provisions in the food regulations, with minimal levels of prescription and complexity, to facilitate innovation and continuous improvement of infant formula through scientific research to promote health and wellbeing of infants
   - sufficient information to support informed choice by consumers enabling them to select products which are suitable to the dietary needs of their non-breastfed infant
   - clarity of requirements to facilitate compliance to and enforceability of the Standard, and
   - cost effectiveness to minimise the potential burden on industry and enforcement agencies, and minimise unnecessary cost impact on consumers
   - harmonisation, where applicable and scientifically justified, with international standards to facilitate import of infant formula manufactured overseas.

5. INC recommends adherence to the principles of minimum effective regulation. Any proposed changes to regulation warrant a proper evaluation including risk analysis to quantify the evidence in terms of risk to infants to ensure restrictions are not applied that are out of proportion to diminishingly small probabilities of harm.

6. In responding to CP2, we have located questions with the issues covered in the order they appear in CP2.

Comments and Responses to questions

2 General composition issues

7. In Table 2.1 covering Submitter comments on general compositional issues FSANZ proposes to overcome technical calculation errors identified in the nutrient composition specified in Codex STAN 72-1981 by aligning with the minimum or maximum values in this Standard as stated in units per 100kJ. INC requests that instead, FSANZ aligns with the units stated per 100kcal multiplied by 4.18. This is because the limits in Codex STAN 72-1981 were set on a kcal basis and the limits per 100kJ listed within it were subsequently calculated from the kcal figures, in some cases incorrectly. This approach will result in better alignment the revised Standard 2.9.1 with Codex STAN 72-1981. INC notes that FSANZ has adopted this approach with respect to revised proposed minimum protein level and recommends that this approach is applied universally.

8. INC also recommends that limits on nutrient composition are consistently stated to 2 significant figures (with exceptions like energy, where more significant figures are warranted, stated to 3 significant figures).

Other Comments

Follow-on Formula

9. Standard 2.9.1 covers Follow-on Formula for infants from 6-12 months as well as Infant Formula and IFPSDU. INC advocated that Follow-on formula be included in the scope of P1028 in its response to P1028 CP1 2021. FSANZ has since advised that the scope of P1028 will be expanded to include Follow-on Formula. In order to assist with this scope extension, INC has considered the appropriateness of the compositional proposals in CP2 for Follow-on Formula.

Potential renal solute load

10. INC recommends the removal of the current limit on potential renal solute load (**PRSL**) for follow-on formula at the same time as changes are introduced in relation to infant formula, implementing the outcomes of P1028. This would better align with the Codex infant formula standard, the Codex follow-up formula standard and EU requirements for follow-on formula, none of which set a limit for PRSL.

11. PRSL is mainly determined by the protein content. It is INC's view that the protein requirements for follow-on formula suffice without the need for an additional PRSL requirement. Furthermore, Fomon et al. (2000) states that healthy infants consuming a predominantly liquid diet have a sufficient renal concentrating ability to maintain water balance even if the diet would provide a PRSL comparable to cow's milk (46 mOsm/100 kcal or 11 mOsm/100kJ).

12. Follow-on formula is not introduced before 6 months of age, and evidence from the WHO states that from the age of 4 months infants have a matured renal function and metabolic interconversion system which can manage a higher dietary protein content (Michaelsen et al. 2003). As such, none of the Codex STAN 72-1981, the revised draft Codex FUF Standard or the EU infant formula regulation, stipulate provisions for PRSL in their provisions (SCF 2003, EFSA 2012).

Different requirements for Follow-on formula

13. Throughout this submission, INC has noted parameters for which it is considered that different limits should apply or be considered for Follow-on formula than those advocated for infant formula. For convenience these are listed below:

- Protein minimum
- Protein maximum
- Depending on protein maximum applied for Follow-on formula, INC may recommend some mineral maximums are reconsidered
- When DHA is added, the requirement for DHA to be no less than arachidonic acid
- Vitamin D maximum
- Calcium GUL
- Iron minimum
- Phospholipid upper limit (**UL**)
- Choline, carnitine and inositol retained as voluntary rather than mandatory.

Guidance Upper Limits (GULs)

14. INC notes that GULs are referred to in the consultation document. In CP2 (p 53), in the micronutrient section, it is stated that these are, "recommended maximum amounts," and, "are not binding and serve as guidance for industry in deriving formulations." Currently guideline maximum amounts of vitamins and minerals in infant formula products are listed in Schedule S29—10. They are not referred to as GULs. To better align with Codex standards, it is recommended that the term 'GUL' is used and defined (as described in CP2) within the Food Standards Code replacing the use of guideline maximum amounts.

Optional ingredients

15. P1028 provides an opportunity to take a holistic look at Standard 2.9.1 as well as the specific requirements therein. INC recommends that the inconsistent approach to the voluntary addition of oligosaccharides is acknowledged and addressed as part of the Review of Standard 2.9.1 or as a subsequent work outcome of P1028. For example, 2'-FL and LNnT are permitted to be *used as a nutritive substance* and listed in Schedule S29—5. By contrast, galacto-oligosaccharides (**GOS**) and inulin-type fructans are noted as specific exceptions in the definition of '*used as a nutritive substance in 1.1.2-12 (c)':*

> (c) any substance (other than an inulin-type fructan, a GOS or a substance normally consumed as a food) that has been concentrated, refined or synthesised, to achieve a nutritional purpose when added to a food.

16. Restrictions on the use of GOS and inulin-type fructans are set out in the body of Standard 2.9.1. These different approaches have arisen due to historical issues rather than technical considerations and the Food Standards Code will be more consistent and coherent if this anomaly is removed.

17. Further, INC considers P1028 provides an opportunity to consider if the term "used as a nutritive substance," approach within the Food Standards Code, as currently used for most permitted optional ingredients used in infant formula products, should be discontinued. Replacement with an approach that is more closely aligned with the "Optional Ingredient," approach used by Codex would improve harmonisation with Codex and regulations in other jurisdictions. The current "used as a nutritive substance" approach is inefficient due to the focus on function and the resources required by industry and regulators to ascertain fit within definition of "used as a nutritive substance"

or not. Given the integral nature of GOS and inulin-type fructans within Standard 2.9.1 and the desired approach to align with Codex to the greatest extent possible, INC suggests these might be presented in the revised Standard 2.9.1 as a list of Optional Ingredients.

Units of Measure

18. In responding to CP2, INC has found it continually frustrating and complex to consider kcal, kJ and conversions. We note that both Codex and the EU present levels used in relation to infant formula and follow up formula in both kcal and kJ. INC strongly recommends FSANZ adopts this approach in Standard 2.9.1 and the associated Schedules.

3 Energy

3.1 Energy Content

19. Standard 2.9.1 prescribes the energy range of 2500–3150 kJ/L based on alignment with Codex provisions at the time of the previous review of the Standard (ANZFA 1999b). The permitted range in Codex STAN 72-1981 has since been narrowed to 2500–2950 kJ/L by lowering the maximum energy content (Codex STAN 72-1981 states the energy maximum as 70 kcal and 295 kJ per 100ml; the kJ energy has been rounded from the calculated value of 293 kJ/100ml). FSANZ proposes to retain the current minimum energy content level and lower the maximum energy content to 2950 kJ/L in line with Codex STAN 72-1981.

20. INC agrees with lowering the maximum energy content to 2950 kJ/L in line with Codex STAN 72-1981.

3.2 Calculation of energy content

21. In the 2016 Consultation paper, a conflict between energy factors used to calculate the energy content provisions in Standard 1.2.8 was discussed. At that time, the proposal was that the energy factors in Standard 1.2.8 should apply to Standard 2.9.1.

22. This issue was resolved in Proposal P1025 – Code Revision. Schedule 29—2 now states that the energy content must be calculated using energy contributions from fat, protein, and carbohydrate with the relevant energy factors set out in Schedule 11—2. INC notes the issue has been resolved.

4 Protein

4.1 Calculation of protein content

23. FSANZ considered 2 options in CP2:
    - *Option 1:* Adopt 6.25 as the NCF for all protein sources.
    - *Option 2:* Adopt all three NCF (5.71, 6.25, 6.38).

24. FSANZ proposes that Option 1 is the most practical option and should be adopted into Standard 2.9.1.

25. Regarding Option 2, INC appreciates FSANZ has attempted to find a flexible approach in allowing choice for industry to harmonise with international standards which use a NCF of 6.25 for infant formula, or to utilise science-based conversion factors, ie 5.71 for soy based infant formula, or 6.38 for dairy-based infant formula.

26. INC can support flexibility in the use of 5.71 or 6.25 for soy based infant formula (with appropriate modification of the minimum protein level), and flexibility in the use of 6.38 for any dairy/whey formula (status quo) or 6.25 to align with Codex. INC does not support that whey-based infant formula is distinguished from other dairy infant formula in the choice of NCFs. INC considers that either 6.38 or 6.25 could be used for all dairy formula, regardless of whether whey-based or other dairy formula. If FSANZ was to proceed with Option 2, INC would only be supportive of this approach if whey vs other dairy formula NCFs were not distinguished.

27. The rationale FSANZ has applied in distinguishing NCFs in whey-based from other dairy formula is not clear. Such an approach was not outlined in the 2019 JEMNU Expert Panel recommendations. INC considers there is insufficient scientific basis to support FSANZ's novel approach. We refer to a recent publication by Elgar et al (2020) with a specific focus on a range of commercial whey products using different methods for protein determination. This continues to highlight that an NCF for whey ingredients is similar to other dairy products.

28. INC considers the FSANZ summary of the 2019 JEMNU Report recommendations incomplete as two Options were proposed by JEMNU, with the same NCF for soy regardless of which Option was selected. Report recommendations were dependent on the definition of protein for infant formula, and consideration of protein in infant formula was defined only as amino acids, or a more holistic view of total protein. INC continues to support a holistic view of total protein, acknowledging that dairy protein has total nutritional benefits, not just its protein components individually.

29. In summary, at this stage as currently drafted, INC considers Option 1 preferable, due to the further issues that would need to be worked through for Option 2. Option 1 should be updated to align with the full Codex STAN 72-1981 NCF footnote.

4.2 Protein range

4.2.1 Cows' milk-based

30. CP2 states that the Food Standards Code and Codex STAN 72-1981 are already aligned for the protein permitted range for infant formula based on cows' milk protein (0.45 g/100 kJ minimum to 0.7 g/100 kJ maximum). FSANZ noted that a technical adjustment had been requested be made to the minimum and maximum amounts to correct what was considered to be an error in converting kcal to kJ in Codex STAN 72-1981. The correction would support a protein range of 0.43 g/100 kJ to 0.7 g/100 kJ based on the equivalence factor of 1 kcal = 4.18 kJ.

31. FSANZ proposes to prescribe a permitted protein range of 0.43 – 0.7g/100 kJ for cows' milk-based infant formula.

32. INC agrees with the FSANZ proposal for a protein range of 0.43 – 0.72 g/100kJ (maximum corrected to two significant figures, in this case two decimal places), aligned with recent international regulations. However, INC opposes this range being applied only to cows' milk-based formulas. INC recommends that this range is applied for all milk based infant formula products.

33. The technical correction of the FSANZ minimum allows harmonisation with Codex and EU recipes, particularly for low protein products. A range of clinical studies have demonstrated the safety and suitability of low protein formula (eg Koletzko et al, 2009;

Raiha et al, 2002; Turck et al, 2006; Alexander et al, 2016). INC agrees that it remains appropriate to retain the protein maximum aligned with Codex STAN 72-1981.

4.2.2 Soy-based

34. FSANZ notes that there is unlikely to be infant health issues related to insufficient protein in Australia or New Zealand. However, to get an accurate estimate of the amount of a protein source to be added to meet the minimum, an accurate NCF should be used.

35. FSANZ proposes that the minimum protein amount for soy-based infant formula be 0.54 g/100 kJ. This is based on the use of 6.25 as the NCF. This is consistent with the regulations set under EU Regulation 2016/127 and with the revised draft Codex Standard for FUF.

36. INC is not aware of any indications that soy-based formulas, formulated to Standard 2.9.1, are unable to meet nutritional needs to support normal growth and development.

37. However, INC can accept alignment with EU Regulation 2016/127 and with the revised draft Codex Standard for FuF if the NCF values are aligned. As well, INC notes that the minimum protein proposed by FSANZ for soy-based formula also aligns with Codex STAN 72-1981.

38. INC suggests that consideration is given to the potential for use of other plant proteins in the future and suggests FSANZ may wish to consider adding a footnote similar to footnote 5 in Codex STAN 72-1981 which highlights that other minimum values may need to apply for formulas based on other non-milk proteins. For reference, Footnote 5 from Codex STAN 72-1981 reads:

    5) The minimum value applies to cows' milk protein. For infant formula based on non-cows' milk protein other minimum values may need to be applied. For infant formula based on soy protein isolate, a minimum value of 2.25 g/100 kcal (0.5 g/100 kJ) applies.

39. This footnote was amended slightly for FuF for Older Infants in the revised draft Codex Standard for FuF for Older Infants:

    5) The minimum value applies to cows' and goats' milk protein. For follow-up formula for older infants based on non-cows' or non-goats' milk protein other minimum values may need to be applied. For follow-up formula based on soy protein isolate, a minimum value of 2.25 g/100 kcal (0.54 g/100 kJ) applies.

40. INC suggests the footnote for the Food Standards Code might read:

    For infant formula [products] based on proteins other than mammalian milks or soy, other minimum values may need to be applied.

IFPSDU Protein-substitute based

41. INC notes that FSANZ has not indicated whether it intends to amend the protein maximum for IFPSDU based on protein substitutes.

42. INC considers that the protein range for infant formula based on protein substitutes, should have the same protein range as infant formula based on cows' milk. INC intends to comment further on this area once CP3 is available.

Follow-on Formula

43. INC notes that FSANZ only recently assessed an application (Application A1173) to vary the minimum protein requirement in follow-on formula. INC would support retaining the protein minimum for a milk-based, follow-on formula as no less than 0.38 g/100 kJ. INC suggests that for other follow-on formula, the protein minimums agreed for infant formula should be applied.

44. Amending the maximum protein was beyond the scope of Application A1173. Previously, several submitters including ISDI and INC had supported that the draft revised Codex Standard for FuF for Older Infants adopt a maximum of 0.84 g/100kJ (3.5 g/100kcal). Additionally, this would be aligned to the maximum adopted by China and would support formulation flexibility for products destined for China.

4.3 Protein source

45. FSANZ notes that the recent focus on new proteins to be used in foods, and the potential safety issues associated with their use in infant formulas, has increased concerns about these sources if not approved through the pre-market assessment process. As a result, FSANZ proposes that the protein source be specified to be cows' milk protein, goats' milk protein, protein hydrolysates of one or more proteins normally used in infant formula, and soy protein isolate.

46. INC does not agree with FSANZ's proposed approach to prescribing permitted protein sources. INC notes at the outset that there are infant formula products in the market using protein sources which are not included in the prescribed list of permitted proteins proposed by FSANZ, for example other animal milk such as sheep milk and other plant -based protein such as rice. If FSANZ was to proceed with a prescribed list, further consideration needs to be given to protein sources in products already on the market. It is also currently unclear how this prescribed protein source list would relate to IFPSDU.

47. INC recognises that the proposal for changes to the Food Standards Code must consider future technological developments, including new protein. However, there are already a range of safeguards in place to ensure safety and suitability covered by horizontal standards. For example, novel foods are already required to undergo pre-market assessment and this would include:

> "...foods produced from new sources, or by a process not previously applied to food".

48. INC agrees that the ingredients used in the manufacture of infant formula be proven safe and suitable for use in infant formula products. However, INC does not agree with FSANZ's proposed approach to prescribing permitted protein sources. FSANZ's stated goal is to align with Codex to the greatest extent possible yet this approach to prescription is not aligned with the Codex approach. INC would support, therefore, aligning with the Codex STAN 72-1981 definition of infant formula as a product based on:

> '*milk of cows or other animals or mixture thereof and other ingredients proven to be suitable for infant feeding'*.

49. New sources of protein are already required to be approved through the pre-market assessment process although INC acknowledges that greater clarity around what is

considered ‘novel/nutritive substance’ is needed and supports continuation of the P1024 proposal.

4.4 Protein quality

50. Both Standard 2.9.1 and Codex STAN 72-1981 regulate protein quality through mandating minimum amounts of the amino acids considered essential (and semi essential) for infants. The FSANZ nutrition risk assessment considered that the digestible indispensable amino acid score (**DIAAS**) and protein digestibility-corrected amino acid score (**PDCAAS**) methods for protein quality assessment are ideal methods, however PDCAAS as written is not suitable for use in 0-12 months as it was originally intended for use in 2 years plus (FAO 1991), and the evidence base for DIAAS is incomplete. PDCAAS was modified for use in protein quality assessment for FuF for young children aged 12 months plus (FAO, 2017). However, INC also notes that it is possible to adapt PDCAAS for use in 0-12 months but the amino acid scoring pattern would need to be updated with the breastmilk amino acid reference pattern.

51. INC notes that CP2 (p25) states that the draft revised Codex Standard for FuF does not use breastmilk amino acid composition as the reference protein but rather has adopted PDCAAS. This statement is not fully correct. The draft revised Codex Standard for FuF for Older Infants retains use of breastmilk amino acids as the reference protein but PDCAAS is adopted for Drinks for Young Children.

52. FSANZ proposes to maintain the current requirements for protein quality in infant formula 0 to 12 months by mandating minimum amino acid amounts comparable to breastmilk levels.

53. INC agrees that protein quality for infant formula should continue to be regulated by mandating minimum amino acid amounts comparable to those found in breastmilk. This is consistent with EU Regulation 2016/127 and Codex STAN 72-1981. Also, it is consistent with the draft revised Codex Standard for FuF for Older Infants, 6-12 months.

4.5 Amino acid content

54. Both Standard 2.9.1 and Codex STAN 72-1981 specify minimum amounts of 11 essential and semi-essential amino acids. Both standards specify that isolated amino acids should be added to infant formula only to improve its nutritional quality.

55. In CP2 Table 4.5 ‘Minimum amounts of amino acids’ (p26, CP2), FSANZ has converted Codex values from kcal to kJ using 4.18 and rounding. In the case of both cysteine and methionine, FSANZ has taken kcal values at 2 significant figures and converted these to kJ values at 1 significant figure. This needs to be addressed for consistency of approach in relation to conversions.

56. Minimum amounts are largely aligned for histidine, isoleucine, leucine, lysine, threonine, tryptophan and valine. However, Codex has a different approach to express amounts of the sulphur amino acids (**SAA**) methionine and cysteine, and the aromatic amino acids (**AAA**) tyrosine and phenylalanine.

57. FSANZ proposes to align the minimum amounts of all amino acids with Codex STAN 72-1981. Regarding SAA and AAA, the added requirements to define ratios of methionine to cysteine and tyrosine to phenylalanine is proposed to be included in Schedule 29 as a condition (for example, see EU Regulation 2016/127).

58. INC supports the FSANZ proposal to align the minimum amounts of all amino acids with Codex STAN 72-1981, including combined totals and ratio for SAA, methionine and cysteine, and the AAA, tyrosine and phenylalanine. Inclusion of a combined total and ratio is important to avoid unnecessary fortification. However, the consequence of doing so is that the change for cysteine and methionine means any manufacturers with a cysteine level between 6 and 9 who are fortifying with methionine will need to change the formulations concerned. To avoid these reformulations, the changes for methionine and cysteine could be specified as an alternative to the existing methionine and cysteine provisions. Alternatively, a substantial transition period could be provided to allow the necessary adjustments to be made.

59. INC agrees that the SAA and AAA combined totals and ratios be defined in Schedule 29 in alignment with Codex STAN 72-1981. In addition to the proposals put forward by FSANZ in CP2, this should include the option for clinical evaluation of the suitability for formula with methionine to cysteine ratios greater than 2 as is included in both the Codex STAN 72-1981 and EU Regulation 2016/127. The additional note regarding clinical evaluation of suitability for formulas with methionine to cysteine ratios greater than 2 is important. INC refers to both the Codex and EU Footnotes on this matter (Attachment A). This approach ensures regulations applied do not inadvertently lead to compliance issues for formulas that have been clinically demonstrated as suitable to support infant growth and development.

5 Fat

5.1 Fat content

60. Based on the conclusions of the 2016 nutrition risk assessment, alignment with Codex STAN 72-1981, EU Regulation 2016/127 and fat content levels found in human milk, FSANZ proposes to retain the current minimum level and lower the maximum to 1.4g/100 kJ.

61. INC supports the proposed levels to align with Codex STAN 72-1981 but recommends that in this area, three significant places be applied to support a rounding to 1.44 g/100kJ. This rounded level is slightly less of a reduction from the current 1.5 g/100kJ than 1.4 g/100 kJ. Also, the current minimum is provided to 3 significant places and the maximum should be aligned to this rounding for consistency within this provision.

5.2 Units of expression

62. Based on alignment with Codex STAN 72-1981 and the draft revised Codex Standard for FuF, FSANZ proposes to express the amounts of fatty acids in terms of mg/100 kJ. This applies to LA, ALA and DHA. Limits on lauric acid, myristic acid, and erucic acid will still be prescribed as a percentage of fatty acids.

63. INC agrees with the alignment with Codex fatty acid units as proposed.

5.3 Essential fatty acid composition: LA and ALA

64. Based on the best available evidence specific to the Australian and New Zealand population, the 2021 nutrition risk assessment concluded that use of a minimum amount of LA between 110 mg/100 kJ and 140 mg/100 kJ poses a low risk to infant health. FSANZ acknowledges that there is some evidence to support increasing the LA minimum requirement. However, further information is needed to address the issues surrounding the stability and palatability of infant formula when LA levels are increased.

Moreover, adopting a higher minimum LA level may create some trade barriers as Codex STAN 72-1981 already sets a lower minimum LA requirement.

65. Two options are proposed to best meet: submitters' concerns, agree with the scientific evidence, and align with international regulations:
    - *Option 1:* Adopt EU Regulation 2016/127 minimum LA level of 120 mg/100 kJ.
    - *Option 2:* Retain the current minimum LA level of 90 mg/100 kJ within Standard 2.9.1 (S29—8).

66. FSANZ proposes to align with Codex STAN 72-1981 on the following:
    - the LA maximum (GUL) of 330 mg/100 kJ
    - minimum amount for ALA (12 mg/100 kJ) with no prescribed maximum for ALA
    - LA:ALA ratio range.

    Based on the conclusions of the 2016 and 2021 nutrition risk assessments, the risk to infant health using these amounts is low.

67. Based on the stability and palatability concerns associated with higher LA levels, history of safe use at current levels and no emerging safety or adequacy concerns for infants, FSANZ proposes to retain the current minimum requirement for LA within Standard 2.9.1 (Schedule 29—8).

68. INC supports Option 2 and the retention of the current minimum requirement for LA within Standard 2.9.1 (Schedule 29—8) which equates to 90 mg/100kJ. This is the midpoint between the Codex STAN 72-1981, the recent draft revised Codex Standard for FUF for 6-12 months, and EU levels. It also allows for the lower end of the LA:ALA ratio of 5:1 to be achieved.

69. This position is supported by an expert group in the US and EU in a recent paper (Carlson et al. 2021). The paper by the expert group (including Koletzko, Calder and others) appears to have been a response to the EU increase in LA minimum levels. They argue that, based on available pre-clinical information, there are potential disadvantages of high LA intake in the early postnatal period as it may reduce n-3 LCPUFA synthesis and/or accretion, resulting in lower DHA status (in the absence of preformed DHA). They argue that:

    "it can by hypothesized that lowering the LA content in infant formula, without changing ALA, DHA, and ARA levels, might support an enhanced infant n-3 LCPUFA status and thereby support healthier infant development. Potentially this might lead to further reconsideration of the level of preformed DHA needing to be added to formula."

70. This underlines the need to be cautious in this area. Retaining the status quo, which lies between Codex and the EU on this matter, is a safe approach to take.

Question 3 Do you support retaining the current minimum requirement for LA (9% total fatty acids) in infant formula? Please provide your rationale and any supporting evidence.

71. INC supports retaining the current LA minimum but for this minimum to be stated as 90 mg/100kJ as per FSANZ proposal to specify this limit on an energy basis; and as 375 mg/100kcal in alignment with INC's proposal for both per 100kcal and 100kJ limits to be included for nutrient limits applying to infant formula products. As stated above, this is the midpoint between the minimum specified in both the Codex STAN 72-1981 and the recent draft revised Codex Standard for FUF for Older Infants (6-12 months), and the

minimum level applied by the EU. It also allows for the lower end of the LA:ALA ratio of 5:1 to be achieved.

Question 4 Are there any technical issues related to increasing the LA minimum in Standard 2.9.1 to align with the higher EU Regulation 2016/127 level of 120 mg/100 kJ?

72. When considering the LA content, it is important to take into account the natural variation of fatty acid levels. In order for production to comply with the minimum requirements set, manufacturers must aim for levels higher than the minimum and lower than the maximum levels specified. This means that the minimum levels set are lower than the label survey values conducted by FSANZ in 2021 with the variability being different between manufacturers.

73. If the minimum of LA is set too high, it limits the ability of manufacturers to produce infant formula within the lower levels of the LA:ALA ratio of 5:1. As shown by Koletzko et al. 2009, this ratio has been generally accepted as appropriate to maintain the proper balance between LA and ALA as well as LC-PUFA's and eicosanoids resulting from their metabolism. For example, if a level of 20 mg/100kJ of ALA is wanted, then to achieve a LA:ALA of 5:1, 100 mg/kJ of LA is required. This is not possible if the current EU minimum level of 120 mg/100kJ is applied. However, the current Standard 2.9.1 allows for this level to be targeted.

Question 5 Can you provide data on the LA levels in commercially available infant formula internationally? This information can be provided as 'Commercial in confidence' if required.

74. INC members will provide this information separately.

5.4 Long chain polyunsaturated fatty acids (LC-PUFA) and other LC-PUFA, ratios and sources

75. FSANZ proposes to retain the current voluntary permission for DHA, provided the DHA level does not exceed the AA amount. When DHA is present, the amount should be controlled by adopting the Codex GUL for DHA of 0.5% total fatty acids.

76. Proposed options for sources of LC-PUFA, eicosapentaenoic acid (**EPA**) and AA and ratios of DHA, AA and LC-PUFA are unchanged from the consideration of these in 2016.

77. INC supports retaining the current voluntary permission for DHA addition provided DHA does not exceed AA amount for infant formula. Careful consideration is recommended before extending the requirement for DHA not to exceed ARA to Follow-on Formula.

78. In further considering the draft revised Codex Standard for FuF and EU Regulation 2016/127 requirements for DHA, INC does not support adopting the Codex STAN 72-1981 GUL for DHA of 0.5% total fatty acids.

79. Koletzko et al. (2020) recommends DHA preferably reaches 0.5% fatty acids, therefore 0.5% would be a target in accordance with this recommendation. In 2017, Codex CCNFSDU agreed a GUL of 7.2 mg/100kJ for follow-up formula for older infants (based on 0.5% of fat maximum). The EU has an upper level of 12 mg/100kJ (close to 1% of fatty acids) based on the highest observable levels in breastmilk. The mean levels of DHA in breastmilk are reported to be 0.32% +/- 0.22% (SD) with a range of 0.06-1.4%

(Brenna et al. 2007). INC therefore supports increasing the GUL to align with 1% of fat maximum (14 mg/100kJ) or adopting 12 mg/100kJ as provided for in the EU.

80. INC agrees with the FSANZ proposal in CP2 Section 5.2, that the units for LCPUFA's are updated to an energy basis be aligned with the approach taken for LA and ALA, and under the draft revised Codex Standard for FuF. To be fully aligned limits should be stated per 100kcal and per 100kJ.

5.5 Fat Source

81. Two options are proposed to best meet submitters concerns, agree with the scientific evidence, and align with international regulations:
    - *Option 1:* Retain the current approach which restricts specific fats and no further definition of fat source.
    - *Option 2*: Relax or remove restrictions on specific fats but introduce more definition about permitted sources of fat.

82. FSANZ proposes Option 1 be applied.

83. INC supports Option 1, to maintain the current approach, which restricts specific fats and no further definition of fat source. As is noted in CP2, this is aligned internationally and with the current Food Standards Code.

5.6 Restrictions on certain fats

84. FSANZ proposes, in Section 5.6.1 of CP2 on MCTs, to continue current restrictions on MCTs.

85. This is not supported by INC, nor was it supported in INC's 2016 submission. The reasons have not changed: there is a lack of safety concerns and it is misaligned internationally. INC does not consider that the prohibition of MCTs was reviewed fully under A563 and retained. A563 was seeking, and gained, permission to use MCTs as a processing aid in preparations of permitted fat-soluble vitamins in infant formula products.

86. Submitters on P93 were clear about the use of coconut and palm oil by industry in infant formula products in Australia and New Zealand. The definition of MCTs is considered to mean oils that contain predominantly C8:0 and C10:0 consistent with the P93 report summary statement:

> *"MCT (C6-C10) are triglyercides (oils) composed chiefly of caprylic (C8, 75%) and capric (C10. 21%) acids with a small amount (C6, 4%) of caproic acid.*'

87. A563 also goes into detail of the definition and production of MCTs as per the following:

> *"MCTs are defined in the European Pharmacopoeia as being obtained from the oil extracted from the hard, dried fraction of the endosperm of Cocos nucifera L. or from the dried endosperm of Elaeis guineensis Jacq, and consisting of a mixture of triglycerides of saturated fatty acids, mainly of caprylic acid ($C_8H_{16}O_2$) and capric acid ($C_{10}H_{20}O_2$) and containing not less than 95% of saturated fatty acids with 8 and 10 carbon atom."*

and further

"Production of MCTs - The oil extracted from coconuts contains approximately 9.6 – 18.0 percent of C8:0 and C10:0 fatty acids, while the oil extracted from palm kernels contains approximately 5.0 – 11.2 percent of C:8 and C:10 fatty acids (Codex STAN 210). These oils are hydrolysed to medium chain fatty acids and glycerol. The glycerol is removed and the fatty acids are fractionated by distillation. The fractionated fatty acids are then re-esterified with glycerol to form MCTs."

88. If the restriction on MCTs is to remain, INC recommends the definition be clarified to include 'oil' so the definition might then read:

"*medium chain triglyceride oil means oil containing triacyglycerols that contain predominantly the saturated fatty acids designated by 8:0 and 10:0*."

89. FSANZ proposes, in Section 5.6.2 of CP2 on trans fatty acids (**TFA**), to retain the current restriction for TFA at 4% of total fatty acids.

90. INC supports the proposed approach of maintaining the current restriction of 4% total fatty acids for TFA. However, INC recommends that as an outcome of P1028 that FSANZ considers reviewing the definition of trans fatty acids in the Food Standards Code to align more closely to the Codex definition in which case the TFA maximum could be revisited to align with Codex.

91. FSANZ proposes, in Section 5.6.3 of CP2 on phospholipids, three alternative options for phospholipids:
    - *Option 1:* Restrict the phospholipids content to 2g/L, or
    - *Option 2*: Restrict the lecithin content to 1g/L for infant formula products; or
    - *Option 3*: Both 1 and 2.

92. FSANZ proposes Option 3 be applied, to restrict both phospholipids and lecithin levels.

93. If FSANZ pursues a UL for total phospholipids, INC can support Option 1, but with the limit being a GUL of 2g/L.

94. INC notes that lecithin is a food additive but was not covered in CP1. INC has reservations about the proposal to restrict its use as food additive from the limit currently applied in infant and follow-up formulas in Codex STAN 192-1995 and FSANZ of 5000 mg/kg (approximately equivalent to 5 g/L).

95. We note FSANZ's reference to the EFSA 2020 opinion on the re-evaluation of lecithin as a food additive in infants <16 weeks of age as justification for FSANZ to similarly adopt a reduced lecithin limit of 1 g/L. This limit has been in place in the EU since 1997. However, this opinion details the substantial toxicological data on lecithin that highlights an absence of adverse effects in animal models at high doses, and does not set an ADI. EFSA (2020) instead, and in line with the earlier SCF 1997 assessment, based the safety assessment for lecithin on choline levels in human milk, compared to existing average levels in infant formula, a different approach for a food additive technological assessment noting the small amount of choline to total formula that lecithin contributes.

96. INC considers there is insufficient evidence in the recent EFSA 2020 Report to justify FSANZ adopting a lower lecithin maximum.

97. FSANZ proposes, in Section 5.6.4 of CP2 on other fatty acids: myristic, lauric and erucic acids, to retain the current restrictions in Standard 2.9.1 for these fatty acids.

98. INC supports maintaining the status quo for myristic, lauric and erucic acids.

6 Carbohydrate

6.1 Definitions for carbohydrate

99. FSANZ has not proposed options for carbohydrate definitions as Standard 1.1.2 now sets out definitions for ‘carbohydrate’, ‘available carbohydrate’ and ‘carbohydrate by difference’, terms that are used throughout the Food Standards Code.

6.2 Dietary fibre

100. FSANZ notes that the Food Standards Code is aligned with Codex STAN 72-1981 and EU Regulation 2016/127 in not prescribing methods of analysis for dietary fibre and is not proposing any change to the Food Standards Code in this area.

101. Schedule 29—2 now states that the energy content must be calculated using energy contributions from fat, protein, and carbohydrate with the relevant energy factors set out in Schedule 11—2. INC therefore supports the position to not prescribe methods of analysis for dietary fibre.

102. INC notes that there is inconsistency between the definition of dietary fibre in the Code and internationally. In particular the use of the term “plant” and the list of physiological benefits. GOS has beneficial physiological effects that are not included under the current Code definition which are captured in the Codex definition of dietary fibre. INC would be supportive of a wider review of the definition of dietary fibre to align internationally and to consider other physiological effects such as are included in the EU definition.

103. INC would like to see a clearer understanding of where oligosaccharides like GOS, 2′-FL and LNnT sit in regards to the definition. There is uncertainty about whether they are dietary fibres or just unavailable carbohydrates. We note, for example, that in CP2 (p49, paragraph 1 options and discussion), it appears to be saying that GOS from animal sources or synthesised and other GM -produced oligosaccharides do not meet the definition of dietary fibre. It goes on in paragraph 4 to say that substances which fall within the definition of dietary fibre have been approved to be added to infant formula including GOS, 2′-FL and LNnT.

6.3 Carbohydrate source

104. FSANZ proposes three options for provisions on the source of carbohydrate:
- *Option 1*: Retain current Standard 2.9.1 (no restrictions on carbohydrate source)
- *Option 2*: Adopt limits on sucrose and fructose that are aligned with Codex STAN 72-1981 guidance
- *Option 3*: Adopt guidelines from EU Regulation 2016/127 and set a list of permitted carbohydrates.

105. INC supports Option 1, maintaining the current approach in Standard 2.9.1 and not to include provisions relating to carbohydrate source. There is no failure in relation to safety and no trade barrier relating to this area.

106. In relation to Option 2, if progressed, the proposal is to adopt limits on sucrose and fructose that are aligned with the guidance in Codex STAN 72-1981.

107. It is noted in CP2 that this approach is supported by: safety concerns cited by government submitters, by FSANZ's safety assessment conducted in 2002, and by international requirements that come into place in 2020 that are in line with Codex STAN 72-1981. INC notes, however, that Codex STAN 72-1981 provides the following guidelines which does not include specific limits:

> "*Sucrose, unless needed, and the addition of fructose as an ingredient should be avoided in infant formula, because of potential life-threatening symptoms in young infants with unrecognised hereditary fructose intolerance*."

108. Additionally, the following text is included in the draft revised Codex Standard for FuF for Older Infants:

> "*Sucrose and/or fructose should not be added, unless needed as a carbohydrate source, and provided the sum of these does not exceed 20% of available carbohydrate*."

109. These reflect the international drive to reduce the amounts of sugars (excluding lactose in this case) in products and also to manage sweetness.

110. If Option 2 is progressed, then INC recommends that consideration is given to including the rationale for guidance to avoid the use of sucrose and fructose from both these Codex documents. However, INC also notes that it is important that there is no inference that no sucrose or fructose is permissible in these products as these sugars can be present in low levels in other ingredients, for example fructo-oligosaccharides.

111. INC suggests text along the following lines for consideration:

> "*The use of sucrose, except where needed, and fructose, as direct ingredients should be avoided in infant formula products. This is to address potential life-threatening symptoms in young infants with unrecognised hereditary fructose intolerance, limit sugars other than lactose and manage sweetness*".

112. INC is strongly opposed to a positive list of permitted carbohydrates because it is counter to the approach of minimum effective regulation and takes significant resources (time and human) to maintain currency.

113. INC notes that Standard 2.9.1—8 Restriction on levels of other substances in infant formula products, requires that such products must not contain detectable gluten. It is recommended that, in alignment with Codex, a maximum gluten content is specified of 20 mg/kg (Codex specifies a maximum of 20 mg/kg of gluten for 'gluten-free' foods (CX 118-2015)). The application of non-detection means the goal posts move as analytical methods become increasingly sensitive.

6.4 Permitted range for total carbohydrate content

114. FSANZ proposes to retain the current approach in Standard 2.9.1 which does not specify a permitted range for carbohydrate content.

115. INC supports retention of the current approach of not specifying a permitted range for carbohydrate content.

7 Micronutrients

7.1 Guideline and maximum amounts

116. FSANZ proposes to retain maximums for vitamins A and D, GULs for vitamins K, C, niacin, thiamin, riboflavin, pantothenic acid, B12, and biotin, to change from a maximum to a GUL for vitamins E, B6 and folic acid.

117. In relation to minerals, FSANZ proposes to retain maximums for chloride, sodium potassium, iron, iodine and selenium, to retain GULs for calcium, chromium and molybdenum and to change from a maximum to a GUL for phosphorous, magnesium, copper, zinc and manganese.

118. INC supports maintaining maximums for vitamins A and D and minerals chloride, sodium, potassium and iron. INC notes that a maximum for selenium and iodine is not aligned to Codex and the draft revised Codex Standard for FuF and INC is proposing a GUL for selenium and iodine (see below).

119. INC supports maintaining GULs for vitamins K and C, niacin, thiamin, riboflavin, pantothenic acid, folic acid, vitamin B12, biotin and calcium.

120. INC notes an inconsistency between CP2 Sections 7.1 and 7.3.7. In Section 7.3.7 FSANZ proposes to remove the GUL for chromium and molybdenum for infant formula. INC supports this approach.

121. INC also supports changing maximums to GULs for vitamins E and B6 and minerals phosphorus, magnesium, copper, zinc and manganese as well as selenium and iodine noted above.

7.2 Vitamin equivalents and conversion factors

122. FSANZ proposes, in Section 7.2.1 of CP2 on vitamin A, β-carotene and calculation of retinol equivalents, that vitamin A requirements be expressed as µg RE/100kJ and that β-carotene be excluded from the vitamin calculation.

123. INC supports vitamin A being expressed as µg RE/100kJ and the exclusion of β-carotene from the vitamin A calculation.

124. FSANZ proposes, in Section 7.2.2 of CP2 on folic acid and folate equivalents, that the requirements for folic acid/folate as µg folic acid/100 kJ. The contribution of folate from ingredients will not be included in the permitted range for this vitamin and therefore there will be no need to use DFE as units of expression for folic acid amounts.

125. INC supports the proposal to express folic acid as µg folic acid/100kJ only and supports the non-inclusion of naturally occurring folate.

126. FSANZ proposes, in Section 7.2.3 of CP2 on vitamin E and tocopherol equivalents, that α-TE be adopted as units for vitamin E to indicate the relative activities of natural and synthetic forms of α-tocopherol. FSANZ also proposes that the current Standard 2.9.1 vitamin E requirements relating to the PUFA content of infant formula is retained

127. INC supports the adoption of α-TE as the units for vitamin E to indicate the relative activities of natural and synthetic forms of α-tocopherol. Vitamin E requirements for PUFA are covered in comments relating to Section 7.4.2.

128. FSANZ proposes, in Section 7.2.4 of CP2 on niacin equivalents, that the current requirement in Schedule 29 for niacin be retained.

129. INC supports maintaining the current requirement of preformed niacin.

7.3 Permitted ranges for micronutrients

Permitted range is aligned with Codex

130. FSANZ proposes, in Section 7.3.1 of CP2 on vitamin A (maximum) to retain the current maximum amount for vitamin A in Schedule S29—9.

131. INC supports maintaining the vitamin A maximum and therefore maintaining the current levels for vitamin A. INC notes that the revised Codex Standard for FuFOI applies a higher minimum but INC proposes the same minimum applies to both infant formula and follow-on formula.

132. FSANZ proposes, in Section 7.3.2 of CP2 on vitamin D, to retain the current permitted range for vitamin D on the basis that no safety concerns have been identified using this range, the range aligns most closely with international regulations and is wide enough to be achievable for product formulation and manufacturing.

133. INC supports maintaining the current range for vitamin D for infant formula.

134. INC notes that the maximum for follow-on formula in the more recent EU regulation and draft revised Codex Standard for FUF is 0.72 µg/100kJ. INC recommends reviewing the maximum level of vitamin D for older infants and increasing in line with these international standards.

135. As well, to ensure consistent alignment with the Codex conversion from kcal, (noting INC has commented at the outset that units stated per 100kcal should be multiplied by 4.18), INC recommends rounding the minimum to 0.24 µg/100kJ.

Permitted range is not aligned with Codex

136. FSANZ proposes that the permitted ranges of eleven micronutrients (vitamin E, niacin, pantothenic acid, folic acid, B12, magnesium, sodium, potassium, manganese, calcium and chloride) that are not currently aligned with Codex STAN 72-1981 now be aligned with Codex without further consideration due to no comments being raised by submitters previously.

137. INC supports the alignment of niacin, pantothenic acid, folic acid, B12 magnesium, sodium, potassium, manganese, calcium and chloride to Codex STAN 72--1981. In accordance with INC preferred approach that alignment to Codex is based on the per 100 kcal values adjusted using the 4.18 conversion factor and cited to 2 significant figures, the following updates are proposed:

- niacin minimum 72 µg/100kJ (300 µg/100kcal)
- pantothenic acid GUL 480 µg/100kJ (2000 µg/100kcal)
- folic acid minimum 2.4 µg/100kJ (10 µg/100kcal)
- B12 minimum 0.024 µg/100kJ (0.10 µg/100kcal)
- sodium minimum 4.8 mg/100kJ (20 mg/100kcal)
- manganese minimum 0.24 µg/100kJ (1.0 µg/100kal) and
- calcium GUL 33 mg/100kJ (140 mg/100kcal).

138. The proposal to align Vitamin E range to Codex is acceptable to the INC, however, it would be preferred to take a similar approach to the EU and set a slightly higher minimum of 0.14 mg/100kJ (0.60 mg/100kcal) with no additional vitamin E PUFA requirement, provided that there is an option for IFPSDU to be aligned to Codex. This would result in the removal of the existing conditions around vitamin E PUFA which would be easier to set and check from a compliance perspective.

139. INC notes that the calcium GUL for older infants is 43 mg/100kJ in the draft revised Codex Standard for FuF for Older Infants and INC would support aligning with this higher GUL for calcium for the older age group.

140. FSANZ proposes, in Section 7.3.2 of CP2 on vitamin K, thiamin, riboflavin, vitamin B6 and biotin, that the lower minimum of EU Regulation 2016/127 be adopted for vitamin K; the current minimum for thiamin in Standard 2.9.1 be retained; the EU range for riboflavin be adopted; the minimum for vitamin B6 in Codex STAN 72-1981 be adopted and the EU minimum for biotin be adopted.

141. *Vitamin K* – INC supports adopting the EU minimum for vitamin K and the Codex GUL to provide a range of 0.24-6.5 µg/100kJ. INC notes that FSANZ has reviewed both the EU maximum of 6.0 µg/100kJ (2021) and Codex STAN 72-1981 GUL of 6.5 µg/100kJ (2016) and considers both pose a low risk to infant health. INC supports the alignment with the Codex STAN 72-1981 GUL as this provides the most flexible approach without posing a risk to infant health.

142. *Thiamin* – INC supports FSANZ's rationale to retain the current minimum for thiamin in Standard 2.9.1 of 10 µg/100kJ and to not align thiamin with the Codex minimum of 14 µg/100kJ. As EU 2016/127 minimum is slightly lower at 9.6 µg/100kJ, INC would also support lowering to the EU minimum rather than maintaining the current level in the Code. INC agrees that as the minimum level is lower than Codex there would be no trade implications.

143. INC notes that FSANZ did not review the thiamin GUL in 2021. INC continues to recommend a GUL of 72 µg/100kJ aligned to EU Regulation 2016/127, Codex STAN 72-1981 and the draft Codex Follow-up Formula Standard for Older Infants. INC notes that FSANZ concluded this level was unlikely to pose risk to infant health in 2016.

144. *Riboflavin* – INC supports maintaining the current riboflavin minimum level of 14 µg/100kJ (rather than 14.3 µg/100kJ) which is aligned with the EU minimum rounded to 2 significant places. However, as FSANZ has concluded that the permitted range under Codex would provide a low risk to infant health, INC supports aligning the GUL to Codex at 120 µg/100kJ rather than EU 95.6 µg/100kJ. This allows for formula that may need to comply to both Codex and the EU to do so. It also reduces administration for exceptions to product not conforming to the Food Standards Code for formula that is being exported under the New Zealand *Animal Products Act 1999* which requires documented evidence of levels different to New Zealand for export to be permitted.

145. *Vitamin B6* – INC supports the adoption of the Codex minimum level for vitamin B6 to provide a range of 8.4 – 42 µg/100kJ. The correct calculation of the minimum should be noted as 8.4 µg/100kJ (35 µg/100kcal) rather than 8.5 µg/100kJ and that the GUL is 42 µg/100kJ (175 µg/100kcal) rather than 45 µg/100kJ.

146. INC notes that FSANZ has reviewed both the EU maximum of 41.8 µg/100kJ (2021) and Codex STAN 72-1981 GUL of 42 µg/100kJ (2016) and considers both are unlikely to pose a risk to infant health. INC continues to support aligning with the Codex STAN

72-1981 GUL of 42 µg/100kJ. Also, this aligns with the draft revised Codex Standard for FuF for Older Infants and the EU Regulation 2016/127.

147. *Biotin* – INC supports the adoption of the EU minimum for biotin and alignment with the Codex GUL to provide a range of 0.24 – 2.4 µg/100kJ. INC notes that FSANZ has reviewed both the EU max (2021) and Codex GUL (2016) and considered both unlikely to pose risk to infant health. INC continues to recommend alignment with Codex but could accept maintaining the current Food Standards Code level.

148. FSANZ proposes, in Section 7.3.4 of CP2 on phosphorous, to retain the Codex aligned minimum for phosphorous and to change to a GUL of 24 mg/100kJ.

149. INC supports these proposals for phosphorous (Codex aligned minimum and a GUL) as reflected in our comments below in response to Section 7.4.1.

150. FSANZ proposes, in Section 7.3.5 of CP2 on copper, to align with the Codex range of 8.4-29 µg/100kJ. INC supports the adoption of the Codex range for copper. Noting the minimum content conversion should be corrected to 8.4 µg/100kJ (35 µg/100kcal).

151. FSANZ proposes, in Section 7.3.6 of CP2 on vitamin C, alignment with the maximum level set by Codex STAN 72-1981 of 17 mg/100 kJ. FSANZ notes this will also allow for liquid formula products.

152. On the minimum for vitamin C, INC supports the approach proposed in CP2 proposed options FSANZ table of maintaining the current levels in the Food Standards Code of 1.7 mg/100kJ and not increasing to align with Codex STAN72-1981. On the GUL for vitamin C, INC supports the approach proposed by FSANZ to increase the GUL of vitamin C from 5.4 mg/100kJ to the level in Codex STAN 72-1981 of 17 mg/100kJ.

153. FSANZ proposes, in Section 7.3.7 of CP2 on chromium and molybdenum, alignment of the permissions with Codex STAN 72-1981 by removing the current maximum level (GUL). FSANZ proposes retaining the current permissions for chromium and molybdenum in IFPSDU under Standard 2.9.1—15.

154. INC supports the removal of the current GUL for chromium and molybdenum in alignment with Codex STAN 72-1981 for infant formula.

155. For IFPSDU, INC will defer comment to CP3 when FSANZ has provided further information on the proposed structure of the standard.

156. FSANZ proposes, in Section 7.3.8 of CP2 on iodine, alignment of the minimum amount with EU Regulation 2016/127 of 3.6 µg/100 kJ. This is an increase of the current minimum of 1.2 µg/100 kJ. FSANZ proposes retaining the current maximum set out in Schedule S29—9 as this amount is comparable to expert recommendations and is an amount that manufacturers are able to meet already.

157. The iodine range is an issue for manufacturers. INC notes that increasing the current iodine minimum of 1.2 µg/100kJ to align with the level in EU Regulation 2016/127 of 3.6 µg/100kJ would provide 76% of the iodine NHMRC AI for infants 0 – <6 months but seriously narrows the range for manufacturing (see below).

158. INC requests that further consideration is given to adopting an iodine minimum of 2.5 µg/100kJ, aligned to Codex STAN 72-1981. INC notes that the NHMRC AI for both younger and older infants is higher than that determined by EFSA (70 µg/day) and used in the review of the draft revised Codex Standard for FuF (90 µg/day). Also, INC notes

that in the current review, FSANZ did not consider the contribution from water to the dietary intake of infants as it did in 2016. Finally, INC notes, as we have elsewhere in this submission, that manufacturers do not target the minimum due to the need to allow for raw material, manufacturing and testing variability.

159. In relation to retaining the iodine maximum of 10 µg/100kJ, given there is no UL established for infants 0-12 months of age and FSANZ's conclusion in 2016 was that this would be unlikely to pose a risk to infant health. INC therefore strongly supports aligning the iodine maximum to the Codex STAN 72--1981 level of 14 µg/100kJ. However, INC does not support a maximum but rather a GUL.

160. The iodine content in raw materials (e.g. milk) is very variable and the proposed higher iodine minimum proposed by FSANZ reduces the range which is already difficult for manufacturers to meet. Manufacturers do not target the maximum due the need to allow for variance so the levels in most products will not be near the maximum. INC supports a GUL instead of a maximum level for iodine, to best accommodate for natural and extensive variation and manufacturing capability.

161. FSANZ proposes, in Section 7.3.9 of CP2 on zinc and the Zn:Cu ratio, alignment with the permitted range in Codex STAN 72-1981 which includes a maximum that accommodates the higher concentration of zinc in soy-based formula. FSANZ also proposes that the prescribed Zn:Cu ratio be removed.

162. INC supports alignment with the permitted range in Codex STAN 72-1981 which includes a maximum that accommodates the higher concentration of zinc in soy-based formula. INC also supports removal of the prescribed Zn:Cu ratio for infant formula.

163. FSANZ proposes, in Section 7.3.10 of CP2 on iron, retaining the current minimum and maximum specified in Schedule S29—9. Retaining this broader permitted range accounts for older infants and soy-based infant formula and aligns with the current Australian and New Zealand market. This also allows manufacturers to meet the Codex and EU ranges for iron, while still posing the least risk to infant health.

164. INC has reservations with regard to the retention of the current minimum and can support the retention of the maximum for iron in infant formula. INC does not agree that retention of the current range allows manufacturers to meet both FSANZ and EU ranges. A product designed under both EU and Food Standards Code requirements would have to meet an iron range of 0.20–0.31 mg/100kJ which is not possible. The minimum level of iron 0.20mg/100kJ does not allow European formulated products complying to Codex minimum of 0.11mg/100kJ to be imported directly into Australia and New Zealand without prior reformulation. Consideration of this is particularly important for IFPSDU.

165. Manufacturers do not target the minimum to allow for variation during manufacture and analysis. The recent review of EFSA (2014) allowed for a greater proportion of the iron requirements of older infants to come from complementary feeding. There is a lack of international alignment with the proposed minimum which creates a barrier to trade.

166. INC requests that FSANZ consider widening the range for infant formula to include the Codex minimum (0.45 mg/100kcal and 0.11mg/100kJ) to give flexibility for recipe harmonisation, particularly for IFPSDU.

167. INC can support a range of 0.24 – 0.48 mg/100kJ for follow-on formula which is aligned to the draft revised Codex STAN for FuF for Older Infants.

168. INC notes that FSANZ is seeking further information on setting separate maximum iron levels for soy -based infant formula. INC agrees that the current levels of iron account for older infants and soy-based formula products and that therefore it is unnecessary to set different levels for soy -based formula.

169. FSANZ proposes, in Section 7.3.11 of CP2 on selenium, to increase the minimum from 0.25 µg/100kJ to 0.48 µg/100 kJ and the maximum from 1.19 µg/100kJ to 2.0 µg/100kJ. FSANZ also proposes retention of a maximum, instead of changing to a GUL for selenium.

170. INC accepts FSANZ's rationale to increase the selenium minimum to 0.48 µg/100kJ which aligns with the US FDA CFR §107.100 and the draft revised Codex Standard for FuF for Older Infants.

171. INC's continued position for selenium is to align with the GUL in the recent draft revised Codex Standard for FUF (i.e. 2.2 µg/100kJ) and not set a maximum as currently proposed at 2.0 µg/100kJ. The review of the Codex Standard for FUF reconfirmed the GUL for selenium at 2.2 µg/100kJ. It is understood that no electronic working group members raised issues with this GUL, highlighting the absence of global concern associated with adverse effects in infants at this level.

172. FSANZ highlights the 2018 NZ total diet survey as a demonstration that dietary intakes are meeting the nutritional requirements for selenium in the New Zealand population. INC agrees with FSANZ that the report indicates: 1) infant formula products are a key dietary source of selenium for infants and 2) infants did not have an estimated mean dietary intake in exceedance of the UL for selenium. This raises the question, what is the risk of exceedance of the UL in practical terms of extension to the Codex 2.2 µg/100kJ.

173. FSANZ references in CP2 that alignment with Codex could (not would) exceed the UL and also made comment that there was no evidence of excess intakes or associated adverse health effects. Given the selenium range of breastmilk provided in CP2 can be much higher than the Codex GUL and New Zealand Total Diet Survey estimates infants are achieving only 40% of the UL, an increase is not likely to cause adverse health effects. INC questions the current relevance of the science used in the original development of the Australia New Zealand UL and recommend that these should be reviewed based on more recent evidence.

174. INC noted in its 2016 submission that manufacturers do not generally target the minimum or maximum/GUL especially where overages for nutrient level maintenance over shelf life are not required, as is the case for selenium. Increasing the maximum to the Codex GUL of 2.2 µg/100kJ facilitates trade and the tailoring of formulations to suit populations that may require increased selenium intake.

175. Further, Figure 7.3.11 in CP2 suggests the range for selenium in breastmilk can be observed to be broader than all current regulations.

7.4 Other ratios, equivalents and nutrient interactions

176. FSANZ proposes, in Section 7.4.1 of CP2 on phosphorous and the Ca:P ratio, adjustment of the provision in Standard 2.9.1 to align with Codex's minimum Ca:P ratio of 1:1.

177. INC supports changing from the current Ca:P minimum ratio of 1.2:1 to the Codex minimum for the Ca:P ratio of 1:1, whilst maintaining the existing maximum Ca:P ratio of 2:1.

178. INC supports adjusting the current phosphorus maximum of 25 mg/100kJ to a GUL of 24 mg/100kJ.

179. FSANZ is seeking further information on the need for separate minimum and maximum phosphorus levels for soy-based infant formula. INC considers that the proposed phosphorus range accounts for all infant formula products and there is no need to set different levels for soy-based formula.

180. FSANZ proposes, in Section 7.4.2 of CP2 on vitamin E and the fatty acids ratio, retention of the current permission for vitamin E requirements relating to the PUFA content of infant formula (minimum amount of vitamin E of 0.5 mg per gram of any PUFA).

181. INC supports the FSANZ proposal to not adopt Codex vitamin E requirements in relation to PUFA. However, although maintaining the status quo for vitamin E PUFA requirements would be acceptable, it would be preferred to take a similar approach to the EU and set a slightly higher minimum of 0.14 mg/100kJ (0.60mg/100kcal) with no additional vitamin E PUFA requirement. This is proposed on the basis that there is an option for IFPSDU to be aligned to Codex as an alternative. This would result in the removal of the existing conditions around vitamin E PUFA which would be easier to set and check from a compliance perspective.

182. FSANZ proposes, in Section 7.4.3 of CP2 on copper, vitamin C and the iron: nutrient interaction that the proposed approaches for copper, vitamin C, and iron to be appropriate in regard to the potential interactions between these nutrients.

183. INC supports this approach of maintaining the status quo. As noted above in relation to Section 7.3.9 of CP2, INC also supports removal of the prescribed Zn:Cu ratio for infant formula.

7.5 Permitted forms of vitamins, minerals and electrolytes

184. FSANZ proposes, by way of a column tilted 'FSANZ response (proposed approach)' in Table 7.17 'Submitter comments on permitted forms' (p96 of CP2), approaches for several permitted forms of vitamins, minerals and electrolytes that are recommended for adoption for Standard 2.9.1. INC comments on each of these below.

185. INC supports alignment with the permitted forms in Codex STAN 72-1981 and the approach proposed under Table 7.17, Row 1.

186. INC still does not support the non-alignment with Codex with nicotinic acid and DL-panthenol. INC notes that nicotinic acid is permitted in Food for Special Medical Purposes under the Food Standards Code and in the EU for both infant formula and Food for Special Medical Purposes.

187. INC supports retaining permission for β-carotene as a permitted form of provitamin A and notes that FSANZ proposes to not include β-carotene in the calculation of vitamin A content (Table 7.17, Row 2). In addition, it is suggested that a footnote is included in S29 in relation to S29-7 and S29-9 stating that β-carotene is not to be included in the calculation of vitamin A content.

188. INC supports retention of both vitamin D2 and vitamin D3 as permitted forms of vitamin D (Table 7.17, Row 3).

189. Additionally, calcium-L-methylfolate as a permitted form of folate has not been considered by FSANZ and as this is permitted in Codex in Formula for Special Medical Purposes Intended for Infants (Codex STAN 72-1981 Section B), INC supports its inclusion in the Food Standards Code. Also, this is a permitted form of folate in Foods for Special Medical Purposes in the EU.

190. INC notes that there has been an EU application to extend the use to all infant formula. At the request of the European Commission, EFSA provided a scientific opinion which concluded that calcium L-methylfolate is a source from which folate is bioavailable and that calcium L-methylfolate is safe under the conditions of use in Regulation 2016/127. Also, an extension of the use of calcium L-methylfolate has been put forward as new work to Codex on the basis of the EFSA new scientific opinion (EFSA, 2020). This new EFSA safety and bioavailability assessment included new scientific evidence, in particular evidence from a new intervention study (Troesch B, et al, 2019).

191. In light of the foregoing, INC requests the inclusion of calcium L-methylfolate for IFPSDU and consideration for broader application in due course.

Question 6 Do you support setting a separate iron maximum for soy-based infant formula? Please provide your rationale and evidence to support your answer

192. As noted above, INC requests that FSANZ widen the range for infant formula to include the Codex minimum (0.11 mg/100kJ) to give flexibility for recipe harmonisation. There is a lack of international alignment with the proposed minimum which creates a barrier to trade. However, in relation to setting separate maximum iron levels for soy-based infant formula, INC considers the current maximum level for iron accounts for older infants and soy-based formula products and therefore it is unnecessary to set different maximum levels for soy-based formula.

Question 7 Do you support setting a separate phosphorus range for soy-based infant formula? Please provide your rationale and evidence to support your answer

193. As noted above, INC considers that the proposed phosphorus range accounts for all infant formula products and there is no need to set different levels for soy-based formula.

7.6 Fluoride

194. Current Standard 2.9.1 stipulates that if infant formula contains more than 17 µg of fluoride per 100kJ prior to reconstitution (for powdered or concentrated infant formula product) or more than 0.15 µg of fluoride per 100 mL for 'ready-to-drink' infant formula, a warning statement is required to indicate the potential risk of dental fluorosis should be discussed with a medical professional.

195. FSANZ proposes alignment with Codex in managing fluoride content by specifying a UL for fluoride of 24 µg/100kJ in infant formula prepared ready for consumption and removing the dental fluorosis labelling requirement.

196. INC supports the increase to 24 µg/100kJ and removal of the labelling requirements on dental fluorosis but would remove the statement 'prepared ready for consumption'. As

the main contributor to the fluoride content is water, which manufacturers have no control over, aligning with the Codex maximum of 24 µg/100kJ when reconstituted and prepared ready for consumption, is ambiguous to interpret and enforce. It is not clear whether regulators and manufacturers should assume no fluoride content, average amount of fluoride content or high level of fluoride content in water when calculating levels to determining compliance. The manufacturer might attempt to make provision for this but does not have control over it and since fluoridation varies by region across Australia and New Zealand and almost certainly in export destinations, this is an impossible task.

8 Other optional substances

8.1 Choline

197. FSANZ proposes that choline be listed as a mandatory substance in infant formula with a range of 1.7–12.0 mg/100 kJ, to align with the Codex STAN 72-1981. The proposed approach also notes that the maximum should be presented as a GUL and that choline should be permitted as the following forms in Schedule 29: choline chloride, choline bitartrate, choline, choline citrate and choline hydrogen tartrate.

198. INC supports choline being listed as a mandatory substance in infant formula with a range of 1.7–12.0 mg/100 kJ, to align with the Codex STAN 72-1981.

199. INC notes that choline is still optional under the draft revised Codex Standard for FUF for Older Infants. INC recommends reviewing choline for older infants and supports aligning to Codex and maintaining choline as optional for 6 to 12 months.

200. INC also supports an increase in the permitted forms of choline listed in Schedule 29 such that in addition to already permitted forms choline chloride and choline bitartate, choline, choline citrate and choline hydrogen citrate be added.

8.2 L-carnitine

201. FSANZ proposes that L-carnitine be listed as a mandatory substance in infant formula and should align with the permitted Codex and EU mandatory minimum of 0.3 g/100kJ. FSANZ also proposes that the current maximum level within Schedule 29 (0.8 mg/100kJ) should be retained, however presented as a GUL, with permitted forms L-carnitine hydrochloride and L-carnitine tartrate in Schedule 29.

202. INC supports that L-carnitine should be mandatory in infant formula and should align with the Codex and EU mandatory minimum. However, the minimum content conversion should be corrected to 0.29 mg/100kJ (1.2 mg/100kcal). Notably, L-carnitine is still optional under the draft revised Codex Standard for FUF for Older Infants. INC recommends reviewing L-carnitine for older infants and supports maintaining it as optional for 6 to 12 months.

203. INC does not consider that a GUL is necessary given the absence of an UL, although we appreciate that FSANZ is now proposing a GUL rather than a maximum. Not specifying a maximum **or** GUL would be in line with other international regulations such as Codex STAN 72-1981 and EU Regulation 2016/127.

204. INC has previously set out both nutritional and technical reasons for not setting a limit for L-carnitine. In the absence of indications of any untoward effects of higher L-carnitine intakes in infants, the ESPGHAN (Koletzko 2005) concluded that no maximum level needed to be set.

205. The only source of L-carnitine for this age group would be breastmilk or infant formula thus it is important that sufficient is provided, allowing for natural variation and manufacturing capability. The GUL is likely to be exceeded as a result of natural and variable contribution of L-carnitine from milk ingredients to the infant formula base.

206. Wollard, Indyk & Wollard (1999) analysed the level of L-carnitine in a range of infant formulas. That survey indicated a range of values from 6.9–30.1mg/100g. Assuming an example reconstitution ratio of 13.0g of powder/100ml formula and an energy value of 280 kJ/100ml, the upper figure of the range would be equivalent to 1.4mg L--carnitine/100 kJ. Industry data confirms the natural content of some dairy ingredients used in infant formula is likely to consistently exceed the GUL. In particular, some whey protein ingredients commonly used in infant formula to adjust whey:casein ratios can contribute a large proportion of L-carnitine content. As a result, common dairy ingredients used in export infant formula formulations cannot be used in current Australian and New Zealand formulations limiting flexibility for manufacturers.

207. INC notes that not all manufacturer's currently label the L-carnitine content on products and that the New Zealand *Food for Export - Exemptions from Domestic Compositional Requirements No. 10 2021* lists a number of exemptions for L-carnitine for dairy-based infant formula again supportive of INC concerns regarding the GUL proposed by FSANZ.

208. INC supports the additional inclusion in Schedule 29 of the permitted forms L-carnitine hydrochloride and L-carnitine tartrate.

8.3 Inositol

209. FSANZ proposes that inositol be listed as a mandatory substance in infant formula with a minimum of 1.0 mg/100 kJ and a GUL of 9.5 mg/100 kJ to align with the Codex STAN 72-1981 range. FSANZ also proposes listing the permitted form of inositol as myo-inositol to provide clarity and align with the Codex STAN 72-1981 and EU 2016/127.

210. INC supports the listing of inositol as a mandatory substance in infant formula and a GUL of 9.5 mg per 100kJ. Notably, inositol is still optional under draft revised Codex Standard for FUF for Older Infants.

211. INC recommends reviewing inositol for older infants and supports maintaining it as optional for 6 to 12 months. Aligned with Codex STAN 72-1981.

212. INC recommends FSANZ review the minimum level. In accordance with INC preferred approach that alignment to Codex is based on the per 100kcal values adjusted using the 4.18 conversion factor and cited to 2 significant figures, the minimum value is set at 0.96 mg/100kJ and GUL of 9.6 mg/100kJ. This also aligns with EU Regulation 2016/127.

213. INC supports listing the permitted form as myo-inositol.

8.4 Taurine and lutein

INC notes that CP2 is silent with regard to taurine and lutein which are both listed in S29-5. INC supports no changes to the current voluntary addition permissions for these substances but requests that limits are stated to 2sf and per 100kcal as well as per 100kJ (as recommended for all nutrient limits specified in 2.9.1 and S29 in relation to infant formula products).

8.5 Nucleotides

214. FSANZ proposes retaining both the current permission in Schedule 29 and the maximum total limit of nucleotide-5′-monophosphates prescribed in Standard 2.9.1.

215. In CP2, page 108, it states:

> "The revised Code clarifies that the combined total nucleotide content is intended to include naturally occurring nucleotides which means that not all individual nucleotides can be present in infant formula at their individual maximum amounts from addition alone."

216. INC supports the continued inclusion of nucleotide-5′-monophosphates as optional ingredients.

217. INC does not support retention of minimums for nucleotides and remains of the view expressed in 2016 that Australia and New Zealand are out of step globally in setting a minimum, when added, for nucleotides. No minimums are set by the US, Canada or the EU reflecting that nucleotides are not considered essential nutrients.

218. INC notes that human and other mammalian milks contain free nucleotides with multiple levels of phosphorylation, free nucleosides, RNA and DNA. The concentrations of 'total potentially available nucleotides' are defined by some authors as the sum of free nucleosides, free nucleotides, nucleotide-containing adducts (such as NAD and uridine diphosphate (UDP) glucose) and nucleotide polymers-ve been reported to be around 10.5 (EFSA, 2014). and European mothers (EFSA, 2014).

219. Therefore, for the sake of clarity INC requests that maximum stated of no more than 3.8 mg/100 kJ of nucleotide-5′-monophosphates in 2.9.1—8 is stated as: "no more than 3.8mg/100kJ (16mg/100kcal) of free nucleotide-5'-monophosphates". This change is important to facilitate compliance verification, for example to auditors and regulators in export markets. INC notes that there is an error in the text quoted above from CP2 as the total of the maximums that apply for the 5- mono-phosphate nucleotides that can be voluntarily added is 1.76 mg/100kJ not 0.76 mg/100kJ.

220. Further, INC recommends that FSANZ reconsiders the maximum applied to GMP. Increasing this maximum from 0.12 to 0.40 mg/100kJ (1.7 g/100kcal) is suggested in recognition of the levels of this free mono-phosphate nucleotide found naturally in goat milk-based formulas (Tolenaars et al, 2021) and in alignment with the upper end of average levels found in human milk (EFSA, 2014).

Other Issues

221. In Table 4.5 'Minimum amounts of amino acids' (p26, CP2), FSANZ has converted Codex values from kcal to kJ using 4.18 and rounding. In the case of both cysteine and methionine FSANZ has taken kcal values at 2 significant figures and converted to kJ values at 1 significant figure. A consistent approach is needed for such conversions.

Question 1 In addition to your submissions from previous Consultations for this Proposal, do you have any further comments on how any of our proposed options in this paper would affect market opportunities for infant formula? Please provide evidence of practical barriers and quantify impacts where possible.

Transition

222. The proposed composition requirements will result in reformulation of almost all infant formula products. This will take significant time and resources for all companies that sell and manufacture infant formula in Australia and New Zealand. There are large number of proposed changes and every infant formula product will need to be fully assessed once the revised Standard is finalised to determine the extent of reformulation required.

223. INC notes that FSANZ has conducted a label review against nutrient levels, however this is not reflective of the manufacturing levels as the target and range must consider variance from operations, testing, raw ingredients and degradation across shelf life. Therefore, any change, no matter how small, that increases the minimum or decreases the maximum or GUL may require some change in the formulation and manufacturing specification.

224. By way of example some of the changes are: reduced energy maximum, reduced total fat maximum, increased minimum for pantothenic acid, folic acid, selenium, iodine and L-carnitine, reduced maximum for sodium and potassium, and the GULs reducing for magnesium, copper, zinc, biotin and niacin.

225. Other proposed changes which will impact the formulation include mandating inositol, L-carnitine and choline in infant formula. Also, there are the changes to amino acids and as mentioned these could impact fortification of methionine.

226. In addition to the massive task of reformulating nutrient composition there are also proposed changes in CP1 for additives, contaminants and labelling.

227. Export products from New Zealand require MPI exemptions where such products fail to comply with FSANZ but meet importing country requirements. There are a number of exemptions in place for paediatric products. In light of the number of changes being proposed to composition and also related to additives in CP1, it is likely that some of these exemptions may need to be revised and may no longer be needed or new exemptions may be identified. Industry will need to work with MPI on the appropriate process for review of these exemptions to ensure exports can continue seamlessly. This process adds additional time, cost and complexity for New Zealand manufacturers producing product for export, and further highlights the need for a sufficient transition period.

228. Some IFPSDU also need to update reimbursement registrations which requires additional time and cost when changing formulations. This would require updating both Pharmaceutic Benefit Scheme (**PBS**) in Australia and Pharmac in New Zealand. PBS in particular currently costs just over $12,000 per product for changes to the formulation or over $20,000 if it impacts the listing. It takes over 7 months for notification and acceptance. There is also the time and resources required to prepare submissions. This again highlights the complexity and cost for companies implementing formulation changes and is another reason that a significant transition period is needed.

229. INC proposes a minimum transition period of 5 years followed by a stock-in-trade period. INC considers this would be appropriate given the significant amount of changes proposed and the cost it will take companies to implement. This transition and stock-in-trade period will help ensure companies are able to plan to try and avoid unnecessary additional costs from labels and other food-related wastage (e.g. ingredients with change of formulation, non-compliant product).

IFPSDU Composition

230. Additionally, due to the highly specialised nature of IFPSDU and to enable access and international alignment, a provision that permits a default to the general formulation requirements of a credible regulatory jurisdiction – Codex, EU, US only – should be allowed in situations where IFPSDU are imported from countries that are governed by these overseas jurisdictions. The importation and sale of such products into Australia and New Zealand is otherwise prevented if such a default was not allowed. This is needed as a prevention of sale would lead to a significant feeding gap for these very vulnerable infant populations and significantly higher costs to make the product available.

Question 2 With the proposed approaches for Standard 2.9.1 or Schedule 29 in this Consultation paper, will small or large businesses be disproportionately impacted if a new permission or restriction does not align with international regulations or standards? If so can you specify how by providing quantitative evidence where possible?

231. Since the changes are across the board, then all businesses are impacted. However, reformulation require resources and this could impact smaller businesses more. There will be differences in impacts and whether products are manufactured off-shore etc. The importance of a lengthy transition period AND a stock-in-trade period for these amendments are significant. Coupled with this is that global supplies of packaging are so difficult to secure as to warrant an extended (5 year transition and a separate stock-in-trade period) and for this to be considered vital.

232. Finally, the proposed amendments and the current arrangements should operate in parallel for the transition period.

REFERENCES

Alexander DD, Yan J, Bylsma LC, Northington RS, Grathwohl D, Steenhout P, Erdmann P, Spivey-Krobath E, Haschke F. (2016) Growth of infants consuming whey-predominant term infant formulas with a protein content of 1.8 g/100 kcal: a multicenter pooled analysis of individual participant data. *American Journal of Clinical Nutrition.* Oct;104(4):1083-1092.

Brenna JT, Varamini B, Jensen RG, Diersen-Schade DA, Boettcher JA and Arterburn LM, 2007.Docosahexaenoic and arachidonic acid concentrations in human breastmilk worldwide. American Journal of Clinical Nutrition, 85, 1457-1464.

Carlson S, Schipper L et al (2021). “Perspective: moving towards desirable linoleic acid content in infant formula". *Advances in Nutrition*: American Society for Nutrition, July 2021. EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the essential composition of infant and follow-on formulae. EFSA Journal 2014;12(7):3760.

EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens),Turck D, Castenmiller J, De Henauw S, Hirsch-Ernst KI, Kearney J, Maciuk A, Mangelsdorf I, McArdle HJ,Naska A, Pelaez C, Pentieva K, Siani A, Thies F, Tsabouri S, Vinceti M, Cubadda F, Engel K-H, Frenzel T,Heinonen M, Marchelli R, Neuh€auser-Berthold M, Poulsen M, Sanz Y, Schlatter JR, van Loveren H, Bernasconi G, Germini A and Knutsen HK, 2020. Scientific opinion on calcium L-methyl folate as a source of folate added for nutritional purposes to

infant and follow-on formula, baby food and processed cereal-based food. *EFSA Journal* 2020;18(1):5947, 17 pp. https://doi .org/10.2903/j.efsa.2020.5947.

EC SCF (2003) *Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae*. European Commission Health and Consumer Protection Directorate- General, 2003: Brussels http://ec.europa.eu/food/safety/docs/labelling_nutrition-special_groups_food-children-out199_en.pdf

EFSA (EFSA Panel on Dietetic Products, Nutrition, and Allergies). (2012) Scientific opinion on dietary reference values for protein. *EFSA Journal* 2012 10(2):2557–2613 http://www.efsa.europa.eu/en/efsajournal/pub/2557 Accessed 16 February 2016

Elgar DF, Hill JP, Holroyd SE, Peddie G. (2020). Comparison of analytical methods for measuring protein content of whey protein products and investigation of influences on nitrogen conversion factors*. International Journal of Dairy Technology*. 2020 73(4): 790-794.

FAO (2017). *Protein quality assessment in follow-up formula for young children and ready to use therapeutic foods*. Report of the FAO Expert Working Group, Rome, 6–9 November 2017

FAO (1991). *Protein quality evaluation in human diets*. Report of a Joint FAO/WHO Expert Consultation. Rome, Food and Agriculture Organization of the United Nations, 1991. FAO Food and Nutrition Paper No. 51.

Fomon SJ. (2000) Potential renal solute load: considerations relating to complementary feedings of breastfed infants. *Pediatrics* 2000, 106:128

JEMNU, 2019. The Joint FAO/WHO Expert Meetings on Nutrition (JEMNU): nitrogen to protein conversion factors for soy-based and milk-based ingredients used in infant formula and follow-up formula, July 2019.

Koletzko B, von Kries R, Monasterolo RC, Subías JE, Scaglioni S, Giovannini M, Beyer J, Demmelmair H, Gruszfeld D, Dobrzanska A, Sengier A, Langhendries J-P, Cachera M-F, and Grote V for the European Childhood Obesity Trial Study Group (2009) Lower protein in infant formula is associated with lower weight up to age 2 y: a randomized clinical trial. *American Journal of Clinical Nutrition* 2009, 89:1–10.

Koletzko B, Bergmann K, Brenna JT, Calder PC, Campoy C, Clandinin MT, Colombo J, Daly M, Decsi T, Demmelmair H, Domellöf M, FidlerMis N, Gonzalez-Casanova I, van Goudoever JB, Hadjipanayis A, Hernell O, Lapillonne A, Mader S, Martin CR, Matthäus V, Ramakrishan U, Smuts CM, Strain SJJ, Tanjung C, Tounian P, Carlson SE. (2020) Should formula for infants provide arachidonic acid along with DHA? A position paper of the European Academy of Pediatrics and Child Health Foundation*. American Journal Clinical Nutrition*, 2020 Jan 1;111(1):10-16.

Michaelsen KF, Weaver L, Branca F, Robertson A. (2000) *Feeding and Nutrition of Infants and Young Children: Guidelines for the WHO European Region, with Emphasis on the Former Soviet Countries.* WHO Regional Publications European Series, No 87. Rome, 2000.

Räihä NCR, Fazzolari-Nesci A, Cajozzo C, Puccio G, Monestier A, Moro G, Minoli I, Haschke-Becher E, Bachmann C, Van't Hof M, Carrié Fässler A-L, Haschke F. (2002) Whey predominant, whey modified infant formula with protein/energy ratio of 1.8 g/100 kcal: adequate and safe for term infants from birth to four months. J*ournal of Pediatric Gastroenterology and Nutrition, 2002,* 35(3):275-281.

Tolenaars et al, 2021.Minor dietary components intrinsic to goat milk and goat milk formulas. International Dairy Journal 2021, 117:105012.

Troesch B, Demmelmair J, Gimpfl M, Hecht C, Lakovic G, Roehle R, Sipka L, Trisic B, Vusurovic M, Schoop R, Zdjelar S, Koletzko B. (2019) MEFOLIN Study Group. Suitability and safety of L-5-methyltetrahydrofolate as a folate source in infant formula: A randomized-controlled trial. *PLoS One*. 2019, 14(8):e0216790.

Turck D, Grillon C, Lachambre E, Robiliard P, Beck L, Maurin JL, Kempf C, Bernet JP, Marx J, Lebrun F, Van Egroo LD. (2006) Adequacy and safety of an infant formula with a protein/energy ratio of 1.8 g/100 kcal and enhanced protein efficiency for term infants during the first 4 months of life. *Journal of Pediatric Gastroenterology Nutrition,* 2006, 43(3):364-71.

ATTACHMENT A

Footnotes from Codex STAN 72-1981 and EU Regulation 2016/127

The EU footnote permits methionine:cysteine ratio greater than 2 provided it is clinically tested:

> "For an equal energy value, infant formula manufactured from cows' milk or goats' milk proteins must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section A of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine may be added together if the methionine:cysteine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2. The ratio of methionine:cysteine and of tyrosine:phenylalanine may be greater than 2, provided that the suitability of the product concerned for infants is demonstrated in accordance with Article 3(3)"

Codex footnote: provision for clinical testing of a methionine:cysteine ratio greater than 2 is limited to just a ratio less than 3:

> "For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex I); nevertheless for calculation purposes, the concentrations of tyrosine and phenylalanine may be added together. The concentrations of methionine and cysteine may be added together if the ratio is less than 2:1; in the case that the ratio is between 2:1 and 3:1 the suitability of the formula has to be demonstrated by clinical testing."